## THE UNITED STATES PATENT AND TRADEMARK OFFICE BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Appellants: Damien CAMELOT, et al.

Title: ENCAPSULATED CRYSTALLINE LACTIC ACID

Appl. No.: 10/631,831

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Examiner: Helen F. Pratt

**Art Unit:** 1761

Confirmation

1704

Number:

## APPELLANTS' REPLY TO EXAMINER'S ANSWER

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Sir:

Appellants are submitting this reply brief under 37 C.F.R. § 41.41 in response to the Examiner's Answer mailed on March 17, 2008. Because this reply is being filed within two months of the mailing date of the Examiner's Answer, it is timely filed.

Appellants are requesting an oral hearing, and to that end, Appellants submit with this reply a Request for Oral Hearing and the fee prescribed by 37 C.F.R. § 41.20(b)(3).

## I. ARGUMENT

Claims 1-5, 7-16 and 18-27 stand rejected as allegedly obvious over European Patent No. 0699392 to Chung, *et al.* ("Chung") or U.S. Patent No. 6,153,236 to Wu, *et al.* ("Wu") or U.S. Patent No. 4,537,784 Percel, *et al.* ("Percel") in view of Borsook, H., *et al.*, "The Preparation of Crystalline Lactic Acid," Kerckhoff Laboratories of Biological Sciences, California Institute of Technology, Pasadena, CA, June 7, 1933, pages 449-460 ("Borsook") and Schouten et al., "Low Temperature Crystal Structure and Molecular Conformation of L(+) Lactic Acid," J. Mol. Structure, 323: 165-168 (1994) ("Schouten").

The Examiner alleges, in essence, that it would have been obvious to substitute crystalline lactic acid as taught in Borsook or Schouten for the amorphous lactic acid in compositions taught by Chung, Percel, or Wu. The Examiner reaches this conclusion on an erroneous assumption that solid lactic acid crystals are essentially equivalent to liquid lactic acids made "solid" by coating onto a solid carrier. However, such an assumption ignores the state of the art at the time of invention and overlooks Appellants' discoveries that enabled the present invention where others had failed. Appellants thus respectfully maintain that the present claims are non-obvious and that the rejections should be reversed.

The Examiner's allegation that it would have been obvious to use solid crystalline lactate in lieu of liquid lactic acid embedded onto solid carriers for encapsulation is unreasonably dismissive of the skill of the ordinary artisan. Indeed, if crystalline lactic acid would have been "easy to handle and less expensive than encapsulating liquid lactic acid" as the Examiner suggests, why would one of ordinary skill in the art, *for decades*, resort to "solidifying" a liquid by using a carrier, when the solid (*i.e.*, the crystalline form) was readily available for the same period of time? Examiner's Answer, page 8, last sentence.

In fact, all of the primary references—Chung (1995), Percel (1985), and Wu (2000)—were authored and published no less than half a century after the known crystallization of lactic acid, e.g., Borsook (1933). Each of these references, however, conspicuously fails to teach an encapsulated particle comprising *crystalline* lactic acid, even when lactic acid (or similar acids) are explicitly mentioned in the references as suitable acids for encapsulation.

Appellants submit that the most logical and coherent reason that the Examiner has found no document disclosing the encapsulation of crystalline lactic acid is simple: prior to the present invention, one of ordinary skill in the art did not know how to encapsulate crystalline lactic acid successfully and therefore deemed it not possible. The specification, at paragraph 0022, describes the problem and the inventive solutions, as follows:

[C]rystalline lactic acid particles are very hygroscopic and carry a liquid phase at their surface. The liquid phase at the crystal's surface hampers encapsulation when the lactic acid is not properly wetted by the coating material. It is found that proper wetting can be ensured by adding a wetting agent to the lactic acid crystals. Suitable wetting agents include silica, potato starch, calcium lactate, methyl cellulose and other types of porous food-grade materials with proper particle sizes. Normally between about 0.5 and 5% (w/w) wetting agent based on the total weight of the crystals is used. Another advantage of using a wetting agent is that the handling of the lactic acid crystals has been improved.

In short, the Examiner's contention that one of ordinary skill in the art would have found it obvious to use solid crystalline lactate in lieu of liquid lactic acid embedded onto solid carriers for encapsulation must fail, because one of ordinary skill in that had not solved the problems associated with the hygroscopicity of crystalline lactic acid (*i.e.*, solved by incorporating a wetting agent), which had heretofore prevented the encapsulation of same.<sup>1</sup>

Each of the cited primary reference echoes Appellants sentiment that at the time the present invention was conceived, those skilled in the art believed that it was simply

<sup>&</sup>lt;sup>1</sup> Without being limited to or bound by theory, Appellants believe that the novel addition of a wetting agent with crystalline lactic acid confers upon the crystals of lactic acid a surface tension suitable for encapsulation.

impossible to encapsulate crystalline lactic acid, in part, due to the hygroscopicity of the crystals. Hence, the citation of secondary references that teach the *mere existence* of crystalline forms of lactic acid would have been insufficient to motivate one of ordinary skill in the art to *encapsulate* the crystals, let alone *solve* the problem of encapsulating crystalline lactic acid.

Percel, for example, expressly recognizes "crystalline lactic acid" in the art, yet teaches solely the use of liquid lactic acid, which is preferably "spray[ed] onto a fluid bed of the calcium carbonate [as] a lactic acid solution of at least 80% concentration." Col. 3, ln. 14-20. Wu, similarly, limits its teachings to lactic acid, "being a liquid," that is first applied to a solid carrier. Col. 4, ln. 54-56. Finally, Chung describes encapsulated food "leavening" acids largely for their use in bakery products, where lactic acid is one of the most commonly used leavening acids, yet Chung is entirely silent on encapsulated lactic acids, let alone encapsulated crystalline lactic acid.

In sum, where others had failed for decades, Appellants made a discovery that enabled the present invention. No reference teaches the discovery, and no reference suggests that crystalline lactic acid can be substituted for liquid lactic acid coated onto a solid substrate for encapsulation. In fact, as argued in Appellants' Brief, the prior art teaches away from the

<sup>&</sup>lt;sup>2</sup> The Examiner has repeatedly alleged that "nothing is seen that anhydrous lactic acid is not crystalline, since the water is removed. The calcium lactate is seen to absorb any further amount of water. Also, [Percel] disclos[es] that some flashing of water occurs, which is seen to also make a crystalline product." See, e.g., sentence bridging pages 6 and 7 of Examiner's Answer. Appellants disagree. First, Percel does not teach the use of anhydrous lactic acid, per se. Rather, Percel merely notes that the percent lactic acid in the disclosed compositions were calculated "as [if] anhydrous," that is, without water. Second, even if Percel is believed to teach the use of anhydrous lactic acid, the Examiner's belief that liquid lactic acid can be made "crystalline" merely by spraying same onto a solid carrier and/or subsequently "flashing" some water off is flatly contradicted by the references of record. See, e.g., Borsook, pg. 450-452 (describing the laborious steps needed to form crystalline lactic acid); and Schouten, para. 2 of Introduction (noting "the problems inherent in obtaining single crystals").

claimed invention. Hence, the references of record fail to provide an adequate suggestion to modify the references of record to arrive at the claimed invention.

## II. **CONCLUSION**

Appellants respectfully request that the rejection of claims 1-5, 7-16 and 18-27 be reversed and that the Examiner be directed to issue a Notice of Allowance indicating that claims 1-5, 7-16 and 18-27 are allowed.

Respectfully submitted,

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